WG2 – Post-Market Surveillance & Vigilance

Chair: Jennifer MAK

Co-chair: Kulwant SAINI

Senior Advisor: Jorge GARCIA

No. of Active WG members: 20

Content

- WG2 Membership Updates
- Progress Report
- Work Plan 2012 - 2014

WG2 Membership Updates

- Yorkie CHOW resigned due to posting change and Jennifer MAK took up the chair in May 2013

- Kulwant SAINI retired in Nov 2013 and WG2 acting co-chair being identified

- 20 members (4 from regulatory authorities & 16 from industry) with 4 newly joined members (1 from HK, 1 from India and 2 from Malaysia) in 2013

Progress Report

- **Activities**
  - AHWPTC Leaders Meeting in Bangkok, Thailand (Feb 2013)
  - Telecon between chair and co-chair (May 2013)
  - Telecon among members (Aug 2013)
  - Numerous email correspondence
- **Key Deliverables in 2012 – 2013**
  - Guidance Document : Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Action (AHWP/WG2/F002:2012)
  - Medical Device Adverse Event (AE) Report Form (AHWP/WG2/F001:2012) & in Editable Format

Work Plan 2012 – 2014 (1)

	Work Item	Output	Status	Target Date	Action
1	**Harmonized Definitions of PMS Terms i.e. AE, PMS etc. (N54)**	**Guidance document** Definition & Classification of Field Safety Corrective Actions (AHWP/WG2/F002:2012)	• Finalized Guidance Document uploaded into the AHWP website	Nov 2012	**COMPLETED**
2	**AE Reporting Form**	**Form & Guidance** Medical Device AE Report Form (AWHP/WG2/F001:2012)	• Finalized AE form uploaded into the AHWP website	Nov 2012	**COMPLETED**
3	**Electronic AE Reporting Form**	**Electronic Form** Editable AE Form available for economy members	• Electronic AE form are available in the AHWP website under >Documents> Forms	Nov 2013	**COMPLETED**

Work Plan 2012 – 2014 (2)

	Work Item	Output	Status	Target Date	Action
4	**Safety Alert Dissemination System (SADS) Upgrade**	**Secured SADS**	• 1st Trial run completed	Oct 2013	**PENDING**
			• The list of SADS members being updated	Dec 2013	
			• Secured SADS ready for implementation	Q1 2014	
			• SADS guidance documents to be revised, if necessary	Q2 2014	
5	**AE Reporting Requirements & Timelines for all Stakeholders**	**Proposed Document** AE Reporting Guidance for the Medical Device Manufacturers or its Authorized Representatives (AWHP/WG2/PMS/004)	• Proposed document to be endorsed in 18th AHWP Annual meeting and uploaded into the AHWP website	Q1 2014	**PENDING**
			• AE Reporting Timelines to be developed	Q2 2014	

Work Plan 2012 – 2014 (3)

	Work Item	Output	Status	Target Date	Action
6	**Adopting GHTF/IMDRF FSCA Guidance Document**	**Guidance Document**	• IMDRF doc not yet finalized its draft document on FSCA	TBC	**KEEP IN VIEW**
			• suggested postponing the guidance until the IMDRF document is ready	TBC	
7	**Developing Guidance Document for Proper Disposal of MDs**	**Guidance Document**	• No GHTF/ IMDRF reference currently available	TBC	**KEEP IN VIEW**
			• MD Disposal not relevant to MD regulation in many jurisdications	TBC	
			• Study and see if further proceed to the guidance development	TBC	
8	**Formal Training of SG02/WG2 Guidance Document**	**Awareness & Implementation**	• Training needs finalized 1. Software validation (US FDA) 2. PMS, laying the roadmap (GHTF SG2/ IMDRF) 3. WG2 output implementation on AE/FSCA (WG6, WG2 & IT)	May 2012	**COMPLETED**
			• Communicated to WG6	May 2012	

End

Thank You!